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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,674	03/09/2001	Roberto A. Macina	DEX-0142	9969

7590 05/06/2002
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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,674	MACINA ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input checked="" type="checkbox"/> Other: <i>See Continuation Sheet</i> . |

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I and II. Claims 1-5 and 7, drawn to a method for diagnosing the presence and metastases of gastrointestinal cancer comprising comparing GSG levels, wherein the CSG comprises SEQ ID NO: 1 or 3, respectively, classified in class 424, subclass 9.1. Claims 1-5 and 7 will be examined with Groups I and II to the extent the methods read on the use of a polynucleotide.

III and IV. Claims 1-5 and 7, drawn to a method for diagnosing the presence and metastases of gastrointestinal cancer comprising comparing GSG levels, wherein the CSG comprises a polypeptide encoded by SEQ ID NO: 1 or 3, respectively classified in class 435, subclass 7.21. Claims 1-5 and 7 will be examined with Groups III and IV to the extent the methods read on the use of a polypeptide.

V and VI. Claims 6 and 7, drawn to a method of identifying potential therapeutic agents wherein the said agent binds to a CSG comprising SEQ ID NO: 1 or 3, respectively, classified in class 435, subclass 6. Claims 6 and 7 will be examined with Groups V and VI to the extent the methods read on the use of a polynucleotide.

VII and VIII. Claims 6 and 7, drawn to a method of identifying potential therapeutic agents wherein the said agent binds to a CSG comprising a polypeptide encoded by SEQ ID NO: 1 or 3, respectively, classified in

class 435, subclass 7.1. Claims 6 and 7 will be examined with Groups VII and VIII to the extent the methods read on the use of a polypeptide.

IX and X. Claims 8 and 9, drawn to a method of imaging gastrointestinal cancer comprising administering an antibody raised against a CSG comprising a polypeptide encoded by SEQ ID NO: 1 or 3, classified in class 424, subclass 130.1.

XI and XII. Claim 10, drawn to a method of treating gastrointestinal cancer comprising administering an agent which upregulates CSG, wherein the CSG comprises SEQ ID NO: 1 or 3, respectively, classified in class 530, subclass 387.1. Claim 10 will be examined with Groups XI and XII to the extent the methods read on the use of a polynucleotide.

XIII and XIV. Claim 10, drawn to a method of treating gastrointestinal cancer comprising administering an agent which upregulates CSG, wherein the CSG comprises a polypeptide encoded by SEQ ID NO: 1 or 3, respectively, classified in class 530, subclass 387.1. Claim 10 will be examined with Groups XIII and XIV to the extent the methods read on the use of a polypeptide.

2. The inventions are distinct, each from the other because of the following reasons:
The methods of Groups I-XIV differ in the method objectives, method steps and parameters and in the reagents used.

SEQ ID NO: 1 (1866 base pairs) and SEQ ID NO: 3 (2785 base pairs) are structurally unrelated and encode different products, which are structurally and functionally distinct. The distinct and specific methods utilizing these four different products differ in their modes of action and yield different effects.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. A telephone call was made to Jane Massey Licata on April 26, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1642

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.
April 26, 2002